AMENDMENTS TO THE SPECIFICATION:

On Page 1, please replace the paragraph under "REFERENCE TO RELATED APPLICATIONS" by the following:

This application is a continuation-in-part application of U.S. patent application ~~Ser.~~ No. 10/306,896 ~~filed: 11/29/2002~~ filed on November 29, 2002, now Pat. No. 6,860,691, which is a continuation-in-part of application No. 09/882,072, filed on June 18, 2001, now Pat. No. 6,494,657.

At page 3, replace the paragraph beginning at line 9 by the following:

U.S. Patent ~~Application~~ No. ~~09/541,508~~ 6,276,883 by Unsworth and Waram, entitled "Self Adjusting Screw System", which patent is incorporated herein by specific reference describes various means to meet the requirements set out above. The present invention describes a system that permits higher holding forces to be maintained and in some preferred embodiments does not require adhesives to hold the screw and coil of the system together for the application of torque and radial loading to the coil prior to insertion.

Replace the paragraph beginning at page 3, line 16 by the following:

The present invention is a screw system that maintains purchase and hold in the substrate by maintaining a relatively low and constant force normal to the longitudinal axis of the screw even if and as the substrate recedes away from the screw and substrate interface. This force normal to the ~~said~~ longitudinal axis of the screw can be kept relatively constant and can be established in advance for various specific purposes to prevent unnecessary damage to the substrate into which it is inserted. Also the screw system expands as the substrate recedes maintaining intimate contact between the two. Additionally the screw system may apply a controlled and relatively constant force parallel to the longitudinal axis of the screw, pushing the screw into the hole into

which it is driven and increasing the friction between the screw and the thread into which it driven thereby reducing the chance of the screw turning back out the hole.

Replace the paragraph beginning at page 4, line 15, by the following:

This combination of screw and coil are well known to the art. U.S. Pat. No. 4,712,955 by Reece et al. describes a screw and helicoil system where the screw is larger than the helicoil and forces the helicoil out normal to the longitudinal axis of the coil and screw, utilizing ramp-like threads on the screw and receivers on the inside of the coil. This action creates very strong wedging forces that hold the screw and coil assembly in the hole of the substrate. This method while suitable for some purposes is not suitable where the substrate is likely to recede away from the original interface between the coil and the substrate. As explained above, even thought the wedging forces are very high, they are maintained over a small distance normal to the longitudinal axis of the coil and screw, and drop off dramatically when the substrate recedes away from the ~~said~~ interface.

Replace the paragraph beginning at page 4, line 25 by the following:

The preferred embodiment of the invention includes a coil and screw system, but the coil, by various means tends to expand once it is inserted into a substrate independently, and not by being forced to do so by another element of the attachment system. These means are referred to herein as "expansion means". While expansion is desirable, it must not be at the expense of ~~the loosing~~ loosening of the screw from the substrate as the coil moves away from the screw in response to the coil following the recession of the substrate. ~~The~~ U.S. Patent ~~Application~~ No. ~~09/541,508 by Unsworth and Waram above~~ 6,276,883 referred to above describes means for ensuring that the connection between the screw and coil is maintained under these conditions, and these means can be combined with the preferred embodiments herein described to effect the same purpose.

Replace the paragraph beginning at page 5, line 7 by the following:

Unlike the wedging action of the conventional screw or conventional screw and coil combination, the coil will expand radially a relatively large distance following any recession of the substrate away from the original substrate coil interface and especially if superlastic shape memory alloy (SMA) material is used for the coil the forces exerted by the expanding coil on the interfacing substrate into which the screw and coil are driven will be relatively even, predictable and repeatable. The expanding screw and coil combination will also by various means described below maintain the purchase and hold of the screw and coil combination on the lumen of the substrate into which the ~~said~~ combination are driven.

Replace the paragraph beginning at page 5, line 20 by the following:

Preferred embodiments of the invention may incorporate either those features that tend to expand the coil, once in the substrate; or those features that tend to increase friction between the coil and the screw and draw the screw into the ~~said~~ lumen; or both.

Replace the paragraph beginning at page 6, line 6 by the following:

The second means to effect the expansion of this coil is to use a coil that is made of shape memory alloy (SMA) material that has been shaped set at high temperature to form a coil that has a lumen diameter larger than the outside diameter of the screw around which it will be wound. When the coil is cooled below its martensitic finish temperature, that is it is pliable, it is wound tightly around the outside diameter of the screw, the turns of the coils falling between the interleaved double threads of the screw so that they mesh. The coil will then assume a more compact diameter than ~~it's~~ <u>its</u> heat set size before cooling. When the coil is then heated to a temperature equal to or above its austenite finish temperature the high temperature or larger diameter shape will be recovered and the coil will expand.

Replace the paragraph beginning at page 6, line 16 by the following:

Torquing means can similarly ~~by~~ be imparted into the coil. Torquing occurs where twist is imparted to the wire along the longitudinal wire axis that forms the coil, or in the case of a coil fabricated from a tube, where twist is imparted to the tubular member that forms the coil, along its longitudinal tube axis. Torquing can occur by simply compressing or pulling the coil spring along the longitudinal axis of the gross coil (as distinguished from the longitudinal axis of the member forming the coil). Torquing may also occur in a more direct manner by grasping and twisting part or parts of the coil spring along the axis that runs longitudinally through the wire or tubular member that forms the coil. This special way of imposing torque on the spring is referred to in this patent as "tilting".

Replace the paragraph beginning at page 6, line 25 by the following:

For example, the coil may be made of a wire with a rectangular cross-section, rather than the customary round one, the short sides forming the outside and inside surfaces of the coil and the long sides forming the facing surfaces between the turns of the coil. Such a coil would look like a Slinky-Toy™. These turns, of the Slinky-Toy for example, are flat having the longitudinal axis of their rectangular cross-sections approximately normal to the longitudinal axis of the gross coil. Now if the ~~said~~ cross-sections of these turns, unlike a Slinky-Toy™, were angled in their unloaded state such that their longitudinal axes formed a 45 degree angle with respect to the plane passing normal through the longitudinal axis of the gross coil, each turn of the coil (if it consisted of a solid loop) would form a coned-disk shape. This shape not coincidentally would be similar to that of a belleville washer. If the coil was made of springy material, each turn of the coil would act like a belleville washer if force was applied to move the turns, or tilt their cross-sections from their unloaded angled, coned-disk configuration to their loaded flat configuration (or some configuration having a different angle than the unloaded configuration). Any coil can be tilted, but most convenient are those with cross-sections that provide points of purchase such as a rectangle, diamond, cam or

triangle.

Replace the paragraph beginning at page 7, line 24 by the following:

The second route is to make the coils from shape memory alloy (SMA) material and impart at high temperature, typically in the range of 400-500°C, for nitinol SMA for example, a cross-sectional shape, that will be recovered after the coil is cooled to a temperature equal to or below the martensite finish temperature and then heated to a temperature equal to or above its austenitic finish temperature. The shape so imparted will be such that when it is constrained below the martensitic start temperature and then subsequently heated to or above the austenitic finish temperature it will have tilt imparted into the turns of the coil. Since the SMA material has been heated to or above the austenite finish temperature it will be superlastic and be springy and therefore be able to spring back and as in the preceding example tending to push the screw on which it is turned forward into the substrate. If the high temperature cross-sectional shape is the same as the previous example, that is, the longitudinal axis of the coil cross-section in its unloaded state is angled 45 degrees with respect to the plane passing normal through the longitudinal axis of the gross coil, and while below the martensitic finish temperature is flattened so that the same longitudinal axis of the coil cross-section is parallel to the plane passing normal through the longitudinal axis of the gross coil; and if the coil is then constrained to maintain the ~~said~~ flattened cross-section, when the coil is heated to or above its austenite finish temperature it will become tilted. Once tilted the coil being now superlastic and springy may spring back and as in the previous example tend to push the screw forward into the substrate.

Replace the paragraph beginning at page 8, line 15 by the following:

The turns of the coil can also be corrugated rather than tilted. The coil would meander back and forth so that the ribs of the corrugations would begin at the inside lumen of the coil and radiate or proceed out to the outside surface of the coil, usually normal to the longitudinal axis of the coil, but other angles or curves could be used in some

preferred embodiments as described in the detailed description of the drawings below. This type of treatment would in some preferred embodiments of the invention be applied to the Slinky-Toy™ type of coil, that is one with an approximate square or rectangular cross-section. This treatment could be in addition to or instead of the tilting means elsewhere referred to herein. The means for accomplishing this would be similar to those used to effect the expanding means above. The corrugated coil could be made of springy material and in its unloaded condition could be flattened and restrained by detachable attachment on to the screw. When unloaded the coil would unload into its corrugated form and spring back tending to project the screw further into the hole into which it is driven by reacting against the threads of the lumen of the substrate on one hand, and on the threads of the screw on the other. This springy material would include conventional spring metal plastic or superlastic material, the latter of which is shape memory alloy (SMA) material that is at or above its authentic finish temperature in both its compressed and expanded form. Similarly the material could be made of shape memory metal (SMA) material, this method making use of the shape recovery regime. The recovered shape could be corrugated. The corrugated coil could be flattened into its uncorrugated form at a temperature equal to or below the martensite finish temperature and attached to the screw. When heated to or above its austenitic finish temperature and constrained into its flattened shape, the corrugated shape would be recovered, loaded and be superlastic and when no longer constrained would spring back tending to project the screw further into the hole into which it is driven by reacting against the threads of the lumen of the substrate on one hand, and the threads of the screw on the other. Rather than corrugate the coil, ~~The~~ <u>the</u> coil could of course be a hollow tube and can have a compact and expanded form effect by the same means as the corrugated coil for the same purpose of providing spring-back to move the screw further into the substrate and increasing the frictional forces maintaining the screw in position.

Replace the paragraph beginning at page 9, line 15 by the following:

Finally, tilting means can be additionally applied to any or any combination of methods

above noted by turning the screw inside the coil while the turns of the coil are constrained by the threads of the substrate into which the screw and coil are inserted and the forward progress of the screw is stopped by the head of the screw abutting the ~~said~~ substrate or the tip of the screw striking a part of the substrate that prevents the screw from advancing any further. When this occurs, the threads of the screw will tend to pull the inside of the coil, to which it interfaces, in a direction opposite to the direction the screw is driven into the hole in the substrate. This is especially the case if the turns of the coil are loosely fitted between the interleaved double threads and/or the radial diameter of the coil is greater than the radial diameter of the distal or proximal thread, or both. When the screw is turned no more, and if the ~~said~~ coil is made of spring material the spring-back of the ~~said~~ coil will tend to project the screw further into the hole into which it is driven by reacting against the threads of the lumen of the substrate on one hand, and the threads of the screw on the other.

Replace the paragraph beginning at page 10, line 1 by the following:

As the coil expands, it also unwinds, and therefore if a very long threaded section is required, it is preferable that a series of small coils be placed end to end to make up the long section desired. This will reduce the friction at the coil and substrate interface which might otherwise prevent the coil from unwinding and expanding. These small coils may be separate or detachably attached so that they separate once placed inside the lumen of the ~~said~~ hole in the substrate. The easiest means of making the coils detachably attach is to introduce a crack or groove at intervals along the length of the wire forming the coil, such that separation will occur when the screw is turned sufficiently causing twisting forces to be imparted to the coil.

Replace the paragraph beginning at page 13, line 4 by the following:

FIG. ~~2~~ <u>2a</u> is a cross-sectional view of a screw 4 with two interleaved helical threads 5a and 5b <u>and FIG. 2b is a close-up of alternate helical threads 5a and 5b in cross-section</u>.

Replace the paragraph beginning at page 14, line 3 by the following:

FIG. 7 is a perspective view of the ~~said~~ coil 1 loaded around a cross-sectional view of the screw 4 with the threads 5a and 5b of the screw falling between the turns 2 of the coil. FIG. 7 also shows a method of detachably attaching the proximal end of the coil to the screw 4 by applying a force 18 or 19 to a curved section 16 of the proximal end of the turn of the coil 2.

Replace the paragraph beginning at page 15, line 11 by the following:

FIG. 16a and 16b are cross-sectional views of the screw system that includes an inclined plane 23 that creates shearing forces between coil turns 2 and thread 5b, assisting in the detachment between the two, as the ~~said~~ coil turns 2 are pressed against the thread 5b by the confining substrate 9, as the screw 4 is turned into the substrate 9.

Replace the paragraph beginning at page 15, line 16 by the following:

FIG. 1 illustrates a coil 1, which can have one or more turns 2 and have dimensions required by the use to which it is employed. The cross section 3 can be any shape that provides a purchase to the screw 4 illustrated ~~on Fig. 2~~ in FIGS. 2a and 2b and its threads 5a and 5b that is threaded into the lumen of the ~~said~~ coil 1, as illustrated in FIG. 3, and a purchase for the thread or surface 10 on the inside of the substrate 9 both shown on FIG. 4. The screw includes a means for turning it, in this case a slot 8 in the head 7 of the screw 4. The cross-section can include such shapes as a beveled, rectangle, as shown on FIG. 1, or any other shape that will provide the ~~said~~ necessary purchase to substrate 9 and screw 4. The shape of cross-section 3 will depend largely on the mechanical properties of the substrate and in particular its strength and tendency to recede with time from away from the original interface between the coil 1 and the substrate 9. Likewise the cross-sectional shape of the screw 4 and screw threads 5a and 5b, can be of any shape to properly mate with the coil 1 and to allow for

the coil to expand and control the position of the coils with respect to the screw 4 and the substrate 9. The height of threads relative to each other and to the turns of the coil which they bracket can vary depending upon the exigencies of the substrate and use.

Replace the paragraph beginning at page 16, line 16 by the following:

The advantages of using a double thread to bracket the coil are many. First, if the coil is fabricated to spring back 12, as described above, and to push the screw 4 in the direction 14 as shown of FIG. 6, the bracketing threads can maintain the coil in the loaded position, prior to appreciable radial expansion, without recourse to adhesives and provided that the coil has some form of attachment to the screw at the distal and proximal ends to prevent premature expansion; although detachably attaching the coil 4 to the distal or proximal threads or both at other points by various means remains an option in some preferred embodiments of the invention. Once the substrate recedes and the radially loaded coil expands, by means described above, the coil 2a as shown of FIG. 6 is free to spring back and roll over the proximal thread 5a. The fact that the proximal thread 5a is shorter than the distal thread 5b, allows for this spring-back rotation even though the turn of the coil 2 has radially expanded away from the screw 4 only a small distance. This spring back rotation can thus push the screw 4 in direction 14, thereby more securely pushing the screw into the substrate, even at an early stage in the recession of the substrate 9 away from the screw 4. The proximal thread 5a can also be curved 11 as shown ~~on the detail on FIG. 2~~ <u>in FIG. 2b</u> to create the same effect. The curving of the proximal thread allows for it to be larger relative to the distal thread 5b, which for some applications may be an advantage. Both the relative size and shape of the distal and proximal threads can therefore be varied by combining shapes and sizes to suite the screw system to the particular purpose.

Replace the paragraph beginning at page 18, line 4 by the following:

FIG. 6 illustrates the system when the spring coil has been released from its constraints or has been heated to or above the austenitic finish temperature and has recovered its

larger diameter or tilted shape or both. The final turns of the screw 4 may also have loaded additional torque or tilt to the turns that will unwind or spring-back in direction 12. FIG. 6 also illustrates when the substrate 9 has receded from the original interface between the coil and the ~~said~~ substrate, the approximately beveled rectangular cross-sections of the turns 2a of the coil 1 have followed the receding substrate and maintained purchase of the threads of the screw with the coil and in turn the coil with the threads 10 of the substrate 9.

Replace the paragraph beginning at page 19, line 4 by the following:

The means of attachment of the coil 1 onto the screw 4 will be explained in greater detail below, however in order to allow for the screw and coil to be turned together into the substrate, it will be necessary to at least fix the distal end of the coil to the distal end of the screw and such attachment may be detachably attachable. The ~~said~~ detachable attachment can be by use of adhesives, biodegradable adhesives, welds or mechanical connections such as hooks or press fit mortise and tendon or such other means well known to the art. Once in place inside the substrate, the means of attachment, except for perhaps the distal end of the screw and coil, should be detachable so that the coil is free to expand with the receding interface between the coil 1 and substrate 9. This detachment can occur, for example, due to the torquing action imparted on the coil by the tightening of the screw, or by biological degradation of the adhesive bond mentioned above. The methods of attaching the coil to the screw are described in ~~that~~ U.S. Patent ~~Application~~ No. <u>6,276,883</u> ~~09/541,508 of Unsworth and Waram above~~ referred to <u>above</u> and these can all be utilized in the attachment of preferred embodiments of the present invention. However, because the coil is positioned between two interleaved helical threads in preferred embodiments of the present invention, the coil in many cases need only be detachably attached to the screw at the distal and proximate ends of both.

Replace the paragraph beginning at page 19, line 21 by the following:

FIG. 7 illustrates one mechanical method by which the coil 1 might be detachably attached to the screw 4 at the proximal end. The space between the distal and proximal threads could be greater at the proximal end, providing space for the proximal end of the coil 1 to be curved and then tacked 17 by laser welding, spot welding, adhesives or other suitable means well known to the art, to one of the threads, in this case the proximal thread 5a as shown on detail 16a. The point of attachment might be broken by simply turning that part of the screw into the substrate 9 that would exert a force 18 on the curved section 16 at the proximal end of the coil straightening and moving the ~~said~~ proximal end toward the distal thread 5b as shown on the details 16b and 16c of FIG. 7.

Replace the paragraph beginning at page 20, line 1 by the following:

Alternatively, ~~the~~ an operator could ~~simply~~ apply ~~a force 19 to bend~~ force 18 by bending the distal curved tab, for example using gripping means, away from the thread to which it is detachably attached, thereby breaking the attachment and allowing the coil 1 to expand away from the screw 4. As shown on 16c, when the coil 1 expands, the part of the turn 2 tends to move in direction 20.

Replace the paragraph beginning at page 24, line 5 by the following:

In one preferred embodiment of the invention illustrated on FIG. 10a and 10b, a space 21 is provided between the turns 2 of the coil 1 and the thread. This space 21 allows the coil to twist when it is being turned into the confining substrate, thereby reducing the space, and providing the means for separating the detachable detachment between the coil turn 2 and the thread 5b at ~~17b~~ 17a. As this space is reduced, at some point before the space is completely closed, the longitudinal axis of the cross-section of the coil turn 2 will rotate in direction 12 beyond the line 12b normal to the longitudinal axis of the bulk coil 1. As the ~~said~~ coil turn 2 rotates through this line, the twisting force that radially compressed and loaded the coil will no longer act to latch the coil, and the coil, unless otherwise constrained, will move in direction 12 as the substrate 9 recedes away

from the screw 4.

Replace the paragraph beginning at page 24, line 15 by the following:

In some preferred embodiments of the invention the shape of the coil at surface 11b, or the shape of the thread 5b, or both as illustrated on FIG. 11a, is such that a fulcrum point is created. In the preferred embodiment illustrated on FIG. 10a this fulcrum point is created at or near a point of detachable attachment 17a. The purpose of moving the fulcrum point near the distal tip 22 of the thread 5b of this preferred-embodiment is to reduce the force that is required to close the space 21 between the thread and the turn 2 of the coil 1. The closing of this space causes the turns 2 of the coil to twist and break the points of detachable attachment 17a and finally to permit unloading of the tilt and consequent rotation of the turns 2 of the coil in direction 12 beyond the line 12b normal to the longitudinal axis of the bulk coil. Some preferred embodiments of the invention have only one point of detachable attachment 17a between the coil turns 2 and thread 5b at the proximal end of the screw 4, while others have many points or continuous areas of detachable attachment. Some preferred embodiments of the invention include an inclined plane 21a as illustrated on FIG. 16a and 16b. This plane causes the turn 2 of the coil 1 to move in direction 23 as the ~~said~~ turn is pressed against the thread 5b by the confining substrate 9, as the screw 4 is turned into the ~~said~~ substrate 9. This movement in direction 23 causes and/or contributes the shearing action that detaches the detatachable attachment 17a. In some preferred embodiments, surface coatings, such as Teflon™ might be applied to the components of the screw system to enhance the movement of the turns 2 of the coil 4, relative to the screw 4.

Replace the paragraph beginning at page 25, line 15 by the following:

Other preferred embodiments of the invention have little or no space 21 between the coil 2 and the thread 5b as illustrated on FIGS. 12a, 12b, 13, and 14 along all or parts of the coil and thread interface. The latching occurs due to the coil turn being constrained beyond the line 12b in a direction opposite 12, as illustrated in FIG. 12a.

Even though there is no space 21, these embodiments of the invention still are able to latch the tilt in the direction 12a beyond the normal line 12b by radially compressing the coil, by twisting as described above. The unlatching of the tilt occurs only when the constraints maintaining the tilt position and/or the radial compression are removed. These preferred embodiments, having no space 21, rely on one or more detachable attachments between coil 1 and threads 5a, 5b such as illustrated on FIG. 7 and FIGS. 10a, 10b and 10c, usually located at the proximal end of the screw.

Replace the paragraph beginning at page 25, line 26 by the following:

~~There~~ These forces acting in direction 12 and 12a are competitive. By adjusting the geometry of the screw and coil, as well as the materials used, these competing forces can be tailored to meet the requirements of the particular application. The strength of the latch acting to prevent the recoil of the coil in direction 12 will also depend upon the distance the coil is loaded beyond the normal line 12b in direction 12a. In some preferred embodiments the coil 2 would be latched just beyond the normal line 12b, to produce a hair trigger. Other preferred embodiments the coil might be latched further in the 12 direction from the normal line 12b, resulting in a more robust lock that would be resistant to inadvertent unloading of the coil in direction 12.

Replace the paragraph beginning at page 26, line 13 by the following:

Some preferred embodiments include ratcheting elements, including ridges that run continuously or discontinuously on the facing surfaces of the coil turns 2 and the thread 5b, or on only one of them. Other preferred embodiments might also include said ratcheting elements on thread turn 2 and thread 5a, or on only one of them. Other preferred ~~embodimens~~ embodiments might include ratcheting elements on any combination of the faces of the coil turns 2 and ~~thre~~ the threads 5b and 5c. The purpose of these ridges, pits or irregularities is to provide a ratcheting purchase between the ~~said~~ coil turns 2 and thread 5b, so that when the coil 2 moves radially outward it will be less likely to retreat. A preferred embodiment includes ridges that run

longitudinally along the facing surfaces of the coil 2 and the thread 5b, and are shaped to slide over each other, but then engage like a ratchet. The shape or saw-tooth irregularities, complementary ridges and grooves, complementary pits and holes, or other such shapes for ratcheting purposes is well known to the art, and any such shapes could be utilized for the stated purpose. The preferred embodiment utilizes ridges that can be readily be machined into one or both of the ~~said~~ facing surfaces of the ~~said~~ coil turns 2 and thread 5b. FIG. 15a, 15b and 15c illustrate how the coil turn 2 and thread 5b engage as they slide up. Any number of ridges or irregularities, spaced in any manner, may be utilized depending upon the use to which the screw will be put. FIG. 15d illustrates a system with the ridges on only the thread 5b and relies on the bottom edge of the thread 2 to engage the ridges on the thread 5b.

Replace the paragraph beginning at page 27, line 3 by the following:

While the preferred embodiments of the invention latch the turns 2 of the coil 1 against thread 5b, it to be understood that the arrangement might be reversed, reversing the geometry of threads 5a and 5b and the tilt of the ~~said~~ coil turns 2, and latching the coil turns 2 against the thread 5a; and while this would otherwise operate in a similar manner, the turns of the coil would tend to pull the screw 4 out of substrate 9 as the tilt unloads. This might however not be important for some applications, and would at least keep the threads somewhat tight in the substrate and prevent turning-out of the screw due to vibration or other causes, well known to the art.